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10/039,307	10/26/2001	Michael R.S. Hill	P0008969.00	2140

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/039,307	HILL ET AL.	
	Examiner	Art Unit	
	FRANCES P. OROPEZA	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/7/09 (Remarks)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-20,41-47 and 54-61* is/are pending in the application.

4a) Of the above claim(s) *54-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-20 and 41-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction

1. Newly submitted claims 54-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- the independent claim currently being prosecuted recites: A means for adjusting the electrical simulation applied during delivery of the pacing therapy responsive to the one or more physiological parameters of the patient as monitored during delivery of the pacing therapy, and

- the newly submitted independent claim recites: A means for adjusting the parameters of electrical stimulation applied during delivery of the electrical stimulation responsive to the one or more physiological parameters of the patient as monitored during contemporaneous delivery of the pacing therapy.

The newly submitted claims provide new limitations where the pacing therapy is provided contemporaneously with the electrical stimulation, and physiological parameters are adjusted during delivery of the electrical stimulation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. Claims 17, 18, 20, 41, 42, 46 and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over "Obel" (U.S. Patent No. 5,199,428 to Obel et al.) and "Collins" (U.S. Patent No. 5,203,326 to Collins) in view of "Limousin" (FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898 to Limousin).

Obel discloses an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2 providing electrical communication and the stimulation coordinated to resynchronization the heart to protect the myocardium (abstract; column 1, lines 15-24; column 3, lines 8-28, 42-45; column 3, line 62 – column 4, line 26; column 5, lines 25-64).

Obel discloses pacing therapy using an anti-tachycardia pacing system (column 9, line 53 – column 10, line 2) and therapy using a back-up pacemaker (104) (column 6, line 66 – column 7, line 25) that can also provide programmable parameters and alternate pacing modes (column 8, lines 49-62). While conducting pacing therapy, the electrical stimulation is adjusted in response to one or more monitored physiological parameters (column 3, lines 8-13, 20-28).

Obel discloses cardiac therapy that decreases cardiac workload (abstract), protects the myocardial cells by reducing the oxygen demand, hence optimizing cardiac output (column 2, lines 9-13), decreases the ischemia and the potentially induced arrhythmias such as brady-arrhythmia and tachycardia (column 2, lines 59-65; column 3, lines 29-33; column 9, lines 53-57), provides pacing therapies to maintain the patient's heart rhythm within acceptable limits (column 3, lines 8-13), ameliorates myocardial ischemia and maintains adequate cardiac rate (column 3, lines 14-15), exerts a tonic effect to slow the heart down and

control tachycardia (column 5, lines 5-18), and treats conditions and arrhythmias of a heart associated with coronary artery disease and myocardial insufficiency (column 10, lines 31-35), these therapy outcomes read to improve cardiac performance and efficiency of the patient's heart.

As to claims 41 and 42, Obel discloses delivering pacing therapy and electrical neural stimulation at the same time. The pacing therapy is controlled by a microprocessor based timing and control circuit such that a previously delivered pacing therapy is altered based on the sensed atrial beat (column 3, lines 8-13, 29-33; column 8, lines 49-59).

As to claims 46 and 47, Obel discloses monitoring heart rate and heart rate variability (column 3, lines 11, 44; column 6, lines 54-58).

It is noted the concepts of treating a patient to improve cardiac performance and efficiency of the patient's heart, and to improve balance of a neurological system of the patient amount to an intended use limitations of which Obel et al. performs or is inherently capable of performing.

As discussed in the previous seven paragraphs of this action, Obel discloses the claimed invention except for the pacing therapy being cardiac resynchronization therapy.

Limousin teaches anti-tachycardia pacing therapy using cardiac resynchronization therapy for the purpose of treating and managing ventricular tachycardia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cardiac resynchronization therapy in the Obel system in order to provide a pacing therapy mode that is

more effective in terminating organized ventricular tachycardia condition than previously known anti-tachycardia pacing therapies, the invention recognizing that shock therapy can be used if the resynchronization therapy is not successful to terminate the tachycardia condition (abstract; figure 1; column 1, lines 11-10, 45-50; column 2, lines 12-21; column 2, line 25 – column 3, line 2; column 4, lines 1-15).

As to a suggestion to combine the references, Obel teach pacing therapy and neural electrical stimulation to decrease the cardiac work load, optimize the cardiac cycle and cardiac output, and treat arrhythmias (abstract; column 5, lines 12-16). Collins teaches autonomic nervous system stimulation to provide therapy for abnormal heart conditions such as arrhythmias (abstract; column 6, lines 1-35). Limousin teaches cardiac resynchronization therapy to manage arrhythimias such as ventricular tachycardia (abstract). The combination of the three references is deemed appropriate and is deemed to teach the instant invention. The rejection of record stands.

The Applicant's arguments filed 4/7/09 have been fully considered, but they are not convincing. While some of the points the Applicant is trying to make are not completely clear to the Examiner, the Examiner's best understanding of the Applicant's arguments is used for the response.

The Applicant argues that:

- Obel delivers nerve stimulation therapies according to pre-programmed parameters which are not varied during their delivery,
- Obel may change the parameters of the nerve stimulation over time based on events prior to the current cardiac therapy, and
- Obel does not adjust the nervous tissue stimulation base upon monitored physiological conditions that are monitored during resynchronization therapy.

The Examiner respectfully disagrees to all three points.

Obel does adjust the nervous tissue stimulation (first sentence of the abstract) base upon monitored physiological conditions (the condition being ischemia (first sentence of the abstract) as monitored against the patient's coronary sinus blood ph and/ or oxygen saturation and/ or electrocardiogram ST elevation (column 3, lines 20-28)) that are monitored during resynchronization therapy (pacing therapies are provided including back-up pacing and synchronized pacing (column 3, line 12; column 8, lines 37-47). The Limousin reference is incorporated in rejection of record to teach cardiac resynchronization therapy (column 2, line 25 – column 3, line 2).

The parameters are adjusted in real time, hence the nerve stimulation therapy is not preprogrammed, nor does it depend on events prior to the current cardiac therapy.

In response to applicant's argument that the references fail to show a certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., pacemaker activated non-concurrently with nerve stimulation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification

are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

While, as asserted by the Applicant, "the basic premise of Obel" may be "that heart pacing is only necessary during nerve stimulation due to its tendency to either slow the heart rates or trigger other arrhythmias", the Examiner is unclear what point the Applicant is seeking to make and hence the Examiner is choosing not to comment further.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Obel" (U.S. Patent No. 5,199,428 to Obel et al.) and "Collins" (U.S. Patent No. 5,203,326 to Collins) and "Limousin" ((FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898 and Limousin) in view of "Adams" (U.S. Patent No. 5,792,187 to Adams).

As discussed in paragraph 4 of this action, modified Obel discloses the claimed invention except the electrode located external to the patient's body against the skin.

Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body on the skin at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the modified Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension, and anxiety is controlled (abstract; figures 4; column 2, lines 48-55; column 3, lines 1-8, 45-48; column 7, lines 11-24). It is noted both electrical and electromagnetic pain suppression systems are well know in the art, and absent any teaching of criticality or unexpected

results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

6. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Obel" (U.S. Patent No. 5,199,428 to Obel et al.) and Collins (U.S. Patent No. 5,203,326 to Collins) and "Limousin" ((FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898 to Limousin) in view of "Sjostrand" (U.S. Patent No. 3,650,277 to Sjostrand et al.).

Obel discloses an apparatus to influence blood pressure, (col. 3 @ 62-64).

As discussed in paragraph 3 of this action and in the previous paragraph, modified Obel discloses the claimed invention except using a sensor to monitor systolic blood pressure.

Sjostrand teaches blood pressure modulation using an atrial systolic blood pressure sensor to determine the level of the blood pressure. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an atrial systolic blood pressure sensor in the modified Obel system in order to have an indication how the stimulation treatment was impacting the blood pressure, so appropriate changes in the treatment could be made to optimize the patient's blood pressure (abstract; column 4, line 74 – column 5, line 4).

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl. H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM–5 PM EST; Tuesday, Thursday 9AM–3PM and 9PM–11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/
Patent Examiner, Art Unit 3766
June 21, 2009

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766